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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/963,738 | 09/26/2001 | Naosuke Maruyama | 5576-132 | 9282 |

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[REDACTED] EXAMINER

WHITE, EVERETT NMN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1623

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/963,738 | MARUYAMA, NAOSUKE |
| | Examiner EVERETT WHITE | Art Unit 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed March 31, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) New Claims 17-21 have been added.
 - (B) Claim 1 has been amended.
 - (C) Comments regarding Office Action have been provided drawn to :
 - (a) 112, 2nd paragraph rejection, which has been maintained for the reasons of record;
 - (b) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 1-21 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low-substituted" in Claims 1, 2, 10-16 and 21 is a relative term, which renders the claim indefinite. The term "low-substituted" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of this term cannot be determined which renders the claims indefinite. Claims 3-9 and 17-20 are also rejected since these claims do not correct this error.

5. Applicant's arguments filed March 31, 2003 have been fully considered but they are not persuasive. Applicants amended the claims in order to over come the rejection. However, the amendment as set forth does not described the term "low-substituted". Claim 1 should be amended to include the recitation "having a hydroxypropyl content in the range from 5 to 16% by weight" (see the 1st sentence on page 6 of the instant specification).

Claim Rejections - 35 USC § 103

6. Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu (WO 98/53798) in view of Koyanagi et al (US Patent No. 3,852,421) for the reasons disclosed on pages 3-5 of the Office Action mailed December 23, 2002.

7. Applicant's arguments filed March 31, 2003 have been fully considered but they are not persuasive. Applicants argue against the rejection on the grounds that the Shimizu reference is not directed to a base material for dry direct tableting that is obtained by impregnating low-substituted hydroxypropyl cellulose having a hydroxypropyl [cellulose] content in the range from 5 to 16% by weight with a sugar or sugar alcohol and then drying the product resulting therefrom. This argument is not persuasive because the Shimizu reference does disclose a composition comprising a sugar alcohol such as sorbitol and erythritol, and a low-substituted hydroxypropyl cellulose having hydroxypropyl group contents of 7.0 to 9.9 % by weight, the sorbitol and erythritol being analogous to the sorbitol and erythritol recited in the instant claims and the hydroxypropyl group contents of 7.0 to 9.9% falling within the range of the amount of the hydroxypropyl content of 5 to 16% that is set forth in the instant claims. Arguments presented by Applicants that the Shimizu reference does not indicate that the base material will be used for dry direct tableting as set forth in the claims is not persuasive since a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Furthermore, the Koyanagi et al patent shows that this utility for low-substituted hydroxypropyl cellulose is well known in the art.

Applicants also argue that the Shimizu reference does not teach or suggest using the sugar alcohol to impregnate the low-substituted hydroxypropyl cellulose component. However, the impregnation of the low-substituted hydroxypropyl cellulose with a sugar or sugar alcohol and drying the resulting product are process limitations in a product claim. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike*

(CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

Accordingly, the rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over the Shimizu reference in view of the Koyanagi et al patent is maintained for the reasons of record.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu in view of Koyanagi et al as applied to Claims 1-20 above, and further in view of Obara (US Patent No. 6,380,381).

Applicant claims a base material for dry direct tabletting, which is obtained by impregnating low-substituted hydroxypropyl cellulose having a hydroxypropyl cellulose content in the range from 5 to 16% by weight with a sugar or a sugar alcohol and then drying the product resulting therefrom. Additional limitations in dependent Claim 21 include the low-substituted hydroxypropyl cellulose in fibrous form.

The information discussed in the Shimizu reference and the Koyanagi et al patent in the above rejection of Claims 1-20 is incorporated into the current rejection. The instant claims differ from the Shimizu reference and the Koyanagi et al patent by claiming that the low-substituted hydroxypropyl cellulose is in fibrous form.

The Obara patent shows that the use of low-substituted hydroxypropyl cellulose in fibrous form to prepare tablets is known in the art (see column 1, lines 27-29).

One of ordinary skill in this art would be motivated to combine the teachings of the Shimizu reference and the Koyanagi et al patent with the teachings of the Obara patent since all the references disclose low-substituted hydroxypropyl cellulose components as part of a composition in tablet form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the low substituted hydroxypropyl cellulose composition of the Shimizu reference and Koyanagi et al patent for dry direct tabletting in view of the recognition in the art, as evidence by the Obara patent, that low substituted hydroxypropyl cellulose in fibrous form serves to increase the hardness of tablets.

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9. Applicant's arguments with respect to claim 21 have been considered but are moot in view of the new ground(s) of rejection.

Summary

10. All the claims are rejected.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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Technology Center 1600